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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,571	07/13/2007	Glenn D. Prestwich	69734-8006.US00	6987

79975 7590 04/26/2010

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EXAMINER	
GOON, SCARLETT Y	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
04/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,571	PRESTWICH ET AL.	
	Examiner	Art Unit	
	SCARLETT GOON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,14,24,25,45-47,49-61,199-203 and 224-246* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-10,14,24,25,45-47,49-61,199-203 and 224-246.

DETAILED ACTION

The preliminary amendment filed on 20 February 2007 in which claims 11-13, 15-23, 26-44, 48, 56-60, 62-198 and 204-223 were cancelled, and claims 237-246 were newly added, is acknowledged.

Priority

This application is a National Stage entry of PCT/US04/40726 filed on 6 December 2004 and claims priority to U.S. provisional application no. 60/526,797, filed on 4 December 2003.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Group I, claim(s) 1-10, 24, 25, 49-55, 199, 200 and 224-246, drawn to a modified glycosaminoglycan in which at least one hydroxyl group of the structure is modified such that the oxygen atom is covalently bound to a hydrazide-reactive group or an aminooxy-reactive group.

II. Group II, claim(s) 14 and 45-47, drawn to a method of making a modified glycosaminoglycan.

III. Group III, claim(s) 61, drawn to a method of producing a crosslinked glycosaminoglycan.

IV. Group IV, claim(s) 201 and 202, drawn to a method for improving wound healing.

V. Group V, claim(s) 203, drawn to a method for delivering living cells to a patient.

Applicants are requested to note that claims 237-241, 244 and 245 are drawn to "the use of". These claims do not conform to U.S. practice and it is unclear as to whether Applicants are intending to claim a compound/composition or a method/process. For restriction purposes, these claims have been interpreted as product claims and have been grouped accordingly.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression “special technical features” is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any). Whether or not any particular technical feature makes a “contribution” over the prior art, and therefore constitutes a "special technical feature," should be considered with respect to novelty and inventive step.

The common technical feature in all groups is a modified glycosaminoglycan comprising a glycosaminoglycan in which at least one hydroxyl group present in the molecular structure of the glycosaminoglycan has been chemically modified so that the oxygen atom of the hydroxyl group is covalently bound to a hydrazide-reactive group or an aminooxy-reactive group instead of a hydrogen atom. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art.

In this case, U.S. Patent No. 5,874,417 to Prestwich *et al.* (IDS dated 19 March 2009) discloses a composition comprising a hyaluronate functionalized with a hydrazide group (column 7, Scheme 1). The functionalized hyaluronic acid compositions forms biocompatible gels or hydrogels (column 5, lines 65-66) and are useful as intermediates for attachment of bio-effecting agents, drugs, peptides, fluorocarbons, oxygen-carrying agents and other molecules of interest (column 6, lines 8-11). U.S. Patent No. 6,387,978 B2 to Ronan *et al.* (PTO-892, Ref. A) further teach that polymers other than hyaluronic acid, such as chitosan and carboxymethyl chitosan, are useful polymers for

forming hydrogels (column 3, lines 1-14). Thus, as carboxymethyl chitosan bears a functional carboxylic acid group similar to hyaluronic acid, and both are taught as being useful in the formation of hydrogels, it would have been *prima facie* obvious for one of ordinary skill to substitute hyaluronic acid as taught by Prestwich *et al.*, with carboxymethyl chitosan, with the expectation that it would similarly yield a hydrazide functionalized chitosan compound.

As a result, no special technical features exist among the different groups because the inventions in Groups I-V fail to make a contribution over the prior art with respect to novelty and inventive step. In conclusion, there is a lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A) Various reactive groups, i.e. hydrazide-reactive group and aminooxy-reactive group, as enumerated in, for example, claims 1, 224, 225, 227, 229, 231, 232, 234 and 235; and

B) Various additional components in the pharmaceutical composition, i.e. bioactive agent or living cell, as enumerated in claims 199 and 200.

Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Specifically, Applicants are further required to elect (i) one reactive group to be selected from the compounds of formula (I), formula (II), formula (III), formula (IV), formula (V), formula (VI), Y-S-S-G or Y-(CO)-NH-NH-(CO)-L-S-S-G; and (ii) whether the pharmaceutical composition comprises a bioactive agent or a living cell, along with the modified glycosaminoglycan.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: claims 1, 14, 24, 61 and 199-203.

Due to the complexity of the above set forth election/restriction requirements, a telephone call was not made to the applicant's agent to request an oral election. See MPEP § 812.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

/SCARLETT GOON/
Examiner
Art Unit 1623